

3.2 WAITING LIST. The following policies pertain to the Waiting List.

3.2.1 Mandatory Listing of Potential Recipients. All candidates who are potential recipients of deceased organ transplants must be listed on the Waiting List.

3.2.1.1 Prohibition of Listings by Non-Members. Only Members will be permitted to have access to the Waiting List. Members may not add candidates to the Waiting List on behalf of transplant centers which are not Members.

3.2.1.2 Permissible Access to UNetSM. The purpose of this policy is to protect confidential and/or sensitive information in UNetSM. UNetSM is the web-based electronic utility used by the OPTN Contractor to conduct the business of the OPTN. UNetSM is comprised of the Match System, all computer software, applications, and security architecture utilized by the OPTN Contractor to fulfill the responsibilities of the OPTN. Institutional Members are permitted access to the Match System. Institutional Members may not allow non-members access to the Match System nor use the Match System on behalf of non members unless all of the following criteria are met:

- i) the non member is a third party assisting the Institutional Member with: facilitating transplants, placing organs for purposes other than transplantation, or reporting data to the OPTN; and
- ii) the member institution has in place a data use agreement (DUA) with the third party that thoroughly addresses issues of confidentiality and security. At a minimum, the DUA must include the following elements:
 - a. rights in data;
 - b. access to patient-identified data;
 - c. use of data;
 - d. data confidentiality procedures;
 - e. disposition of data upon completion of contracted task;
 - f. procedures to protect patient-identified data in the event of a breach, inadvertent or otherwise; and
 - g. remedies in the event of a violation of the data use agreement.

The member institution must maintain a copy of this DUA and provide it to the OPTN contractor upon request.

3.2.1.3 Prohibition for Non-Approved Programs. No Member shall add a candidate to the Waiting List for a transplant procedure for which Member has not received approved program status. Nor shall a Member add another Member's candidate to the Waiting List for a transplant procedure for which the other member has not received approved program status.

3.2.1.4 Prohibition for Organ Offers to Non-Members. Members shall not provide organs to non-member transplant centers except to transplant centers in foreign countries as described in Policy 6.4 (Exportation and Importation of Organs - Developmental Status).

3.2.1.5 Renal and Renal-Pancreas Combination Candidate Listing. In order to list a potential recipient of a kidney or a kidney-pancreas combination transplant on the Waiting List, the potential recipient's complete HLA antigen information (at least 1 A, 1 B, and 1 DR antigen) must be included at the time of listing the potential recipient. This requirement shall not apply to potential recipients listed for combined kidney-nonrenal transplantation, with the exception of kidney-pancreas transplantation. The entry of the complete HLA antigen information for candidates on the Waiting List shall require the use of current World Health Organization (WHO) Nomenclature. (This requirement that WHO nomenclature be used shall be implemented with the implementation of the New Data Collection Forms.)

3.2.1.6 Registration of *In Utero* Transplant Candidates. Registration of an *in utero* transplant candidate on the Waiting List is appropriate only when prenatal diagnostic tests confirm that the *in utero* candidate is viable and medically suitable to receive an organ transplant. The risk of associated complications becomes appropriately low at between 32 and 36 weeks gestation.

An *in utero* transplant candidate shall be listed under a special status code on the Waiting List.

3.2.1.7 In Utero Waiting Time. If an *in utero* candidate is not assigned a thoracic organ transplant prior to delivery on the basis of Policy 3.2.1.6, the candidate's waiting time will recommence from the time of birth with the candidate listed under the regular status code.

3.2.1.8 Waiting Time Modification. Transplant candidates on the Waiting List may have waiting time accrued under a previous Waiting List registration reinstated under the following circumstances:

- i. The candidate was incorrectly removed from the Waiting List, as a result of errors and/or miscommunication between clinical/clerical personnel. The reinstated waiting time shall include time accrued under the previous registration, in addition to the time interval during which the candidate was removed from the Waiting List.
- ii. The candidate was removed from the Waiting List for medical reasons other than having received a transplant and subsequently was relisted for the same organ with the same diagnosis. The reinstated waiting time only shall include time accrued under the previous registration and not the time interval during which the candidate was removed from the Waiting List.

Upon receipt by the Organ Center of a completed Waiting Time Modification Form (with all required information) and verification of the information through review of the candidate's history, Organ Center staff may reinstate the candidate's waiting time.

All other requests for waiting time reinstatement that are not specified under Policy 3.2.3.2 (Waiting Time Reinstatement for Kidney Recipients), or other policies which describe permissible waiting time adjustments, shall be first approved by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the candidate is listed, and then submitted to the appropriate organ-specific committees and Board of Directors for review with appropriate supporting documentation. Notwithstanding the above, however, upon demonstration to the appropriate organ-specific committee that unanimous agreement among the relevant parties cannot be obtained despite efforts to do so, such a request may be submitted with appropriate supporting documentation, including without limitation, reasons provided by the dissenting party(ies) for any disagreement, for consideration despite the lack of unanimous approval. Modification requests for isolated kidney and combined kidney/pancreas waiting time shall indicate and substantiate with supporting documentation that the candidate met waiting time criteria as defined in Policy 3.5.11.1 (Time of Waiting) or Policy 3.5.12.1 (Time of Waiting) as of the listing date requested. Under the circumstances described in this paragraph, waiting time modifications will be made, in the case of requests for modifying kidney or pancreas waiting time, after consideration and approval by the Kidney & Pancreas Transplantation Committee, or, in the case of pediatric (*i.e.*, less than 18 years old) candidates, with approval from the Chair of the Kidney & Pancreas Transplantation Committee to proceed to a subcommittee of the full Committee followed by consideration and unanimous approval by this subcommittee. Pediatric candidate cases addressed by a subcommittee of the Kidney & Pancreas Transplantation Committee will subsequently be referred to the full Committee for consideration of final action as determined appropriate by the Committee and in the case of requests for modifying waiting time for organs other than kidney and pancreas (except as provided in Policy 3.2.1.8.1 (Waiting Time Modification for Urgent Status Candidates)) only upon approval by the Board of Directors, or by the Executive Committee subject to ratification by the Board of Directors. Requests for modifying kidney or pancreas waiting time, along with decisions of the Kidney & Pancreas Transplantation Committee or subcommittee in the case of pediatric candidates, shall be reported to the Board of Directors retrospectively.

3.2.1.8.1 Waiting Time Modification for Urgent Status Candidates. Adjustments will be permitted to the waiting time of Status 1 liver transplant candidates and Status 1A heart transplant candidates registered on the Waiting List if an error or miscommunication occurred in listing, modification, or accidental removal of the candidate, or in renewing the candidate's status. Supporting documentation must be submitted, including a written request from the physician/surgeon in charge of the candidate's care explaining the circumstance along with the

appropriate status justification form and Wait Time Modification Form. Upon receipt of completed documentation, the requested modification will be made. Each case will be reported retrospectively to the appropriate regional review board for consideration.

- 3.2.1.9 Waiting Time Transferal.** For the purpose of this policy, "primary waiting time" shall mean the longest time period a candidate listed on the Waiting List has been waiting for a specific organ transplant procedure, after having met qualifying criteria to accrue waiting time for that organ. A candidate may transfer his/her primary waiting time from one transplant center (Initial Primary Center) to another center (New Primary Center) upon listing of the individual as a transplant candidate by the New Primary Center. After receipt of a Wait Time Transfer Form, the date the candidate first met waiting time criteria (the date from which primary waiting time will be calculated) at the New Primary Center will be modified in UNetSM by the Organ Center as the date the candidate met waiting time criteria at the Initial Primary Center. Subsequent to the receipt of this request, the candidate is to be deleted from the Waiting List of the Initial Primary Center. A notice of the primary waiting time transfer will be sent from the Organ Center to each of the centers involved.
- 3.2.2 Multiple Listings Permitted.** Candidates may be waitlisted at multiple transplant centers. These transplant centers may be located within the same OPO service area. These transplant centers may be located within different OPO service areas.
- 3.2.2.1 Waiting Time Transferal for Multiple Listed Candidates.** For the purpose of this policy, "primary waiting time" shall mean the longest time period a candidate listed on the Waiting List has been waiting for a specific organ transplant procedure, after having met qualifying criteria to accrue waiting time for that organ. A candidate may transfer his/her primary waiting time from one transplant center (Initial Primary Center) to another center (New Primary Center) upon listing of the individual as a transplant candidate by the New Primary Center. After receipt of a Wait Time Transfer Form the date the candidate met waiting time criteria (the date from which primary waiting time will be calculated) at the New Primary Center will be modified in UNetSM by the Organ Center as the date the candidate met waiting time criteria at the Initial Primary Center. The candidate will be assigned a new primary waiting time date in the Waiting List record for the Initial Primary Center which corresponds with the date on which the candidate is listed at the New Primary Center. A notice of the primary waiting time transfer will be sent from the Organ Center to each of the centers involved.
- 3.2.2.2 UNetSM Indication of Multiple Listing.** Transplant centers will be notified through UNetSM that candidates are multiple listed, but will not be notified of the identities of other centers at which the candidates are listed.
- 3.2.2.3 UNetSM Notification of Transplantation or Death of Multiple Listed Candidates.** Transplant centers will be notified through the UNetSM system when a multiple listed candidate has been transplanted or reported as deceased by another center so that all other centers involved can investigate and request removal of the candidate from the center's Waiting List.
- 3.2.2.4 Non-acceptance of Multiple Listing and/or Transferal of Primary Waiting Time.** Every transplant program that does not accept multiple listed candidates and/or does not allow these candidates to transfer their primary waiting time to that center if the candidate so desires, must fully inform the candidate during the transplant evaluation process or sooner.
- 3.2.3 Waiting Time Transferal and Multiple Listing.** Every transplant program must inform every candidate about the options of multiple listing, transferring primary waiting time, and the option to transfer their care to a different transplant center without loss of accrued waiting time, during the evaluation process, provide the candidate with written material on these options, and maintain documentation that this requirement was fulfilled

3.2.4 Match System Access. OPOs are required to use the Match System (UNetSM) for the allocation of all deceased donor organs. The Host OPO must enter required information about the donor (Policies 3.5.7, 3.6.9, 3.7.9, and 3.8.5) and execute the Match System to determine organ allocation priorities. Such information must be entered into the Match System for all deceased donors. The OPO shall be responsible for two separate determinations 1) two samples sent to two labs, or 2) two samples from separate draws sent to the same lab of the donor's ABO type prior to incision and for ensuring the accuracy of the donor's ABO data. The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit. Each OPO shall establish and implement a procedure utilizing the ABO source documents for on-line verification of donor ABO data by an individual other than the person initially entering the donor's ABO data in UNetSM.

Organs shall be allocated only to candidates who appear on a match run. In the event that an organ has not been placed after the organ has been offered for all potential recipients on the initial match run, the Host OPO may give transplant programs the opportunity to update their transplant candidates' data, and the Host OPO may re-run the match system. In any event, the organ shall be allocated only to a candidate who appears on a match run.

If the transplant center deems it necessary to transplant a candidate who does not appear on at least one of the deceased donor's match runs for at least one organ type, such as in the event of a directed donation or to prevent organ wastage, the transplant center must maintain all related documentation and provide written justification to the OPTN contractor upon request. The written justification must include:

- the rationale for transplanting a candidate who did not appear on the match run;
- the reason the candidate did not appear on the match run;
- the center is willing to accept an ECD or DCD organ, as applicable; and
- documentation that the transplant center verified suitability between the donor organ and recipient prior to transplant in at least, but not limited to, the following areas as applicable to each organ type:
 - ABO;
 - Serologies;
 - Donor HLA and candidate's unacceptable antigens;
 - Height; and
 - Weight.

For all deceased donor organs, the organ must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. If an organ is accepted for a candidate who ultimately is unavailable to receive the transplant at his/her listing transplant center in the organ allocation unit to which the organ is being distributed, then the organ shall be released back to the Host OPO or to the Organ Center for allocation to other transplant candidates in accordance with the organ-specific allocation policies. The Host OPO may delegate this responsibility to the Local OPO. Further allocation at the local OPO level must be done according to the match run. The final decision whether to use the organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of that candidate. This will allow physicians and surgeons to exercise judgment about the suitability of the organ being offered for the specific candidate. If an organ is declined for a candidate, a notation of the reason for the decision refusing the organ for that candidate must be made on the appropriate form and promptly submitted.

3.2.4.1 Removal of Kidney Transplant Candidates from Kidney Waiting Lists When Transplanted or Deceased. If a kidney, kidney/pancreas or kidney/islet transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all organ Waiting Lists for that transplanted organ and shall notify the OPTN contractor within 24 hours of the event. If the recipient is again added to a Waiting List for that transplanted organ, waiting time shall begin as of the date and time the candidate is relisted. If the recipient is waiting for a combined kidney/pancreas or kidney/islet transplant and receives only an isolated kidney transplant, the

recipient's accrued kidney waiting time shall automatically be transferred to the isolated pancreas or islet, as applicable, Waiting List.

- 3.2.4.2 Waiting Time Reinstatement for Kidney Recipients.** In those instances where there is immediate and permanent non-function of a transplanted deceased or living donor kidney, the candidate may be reinstated to the Waiting List and retain the previously accumulated waiting time without interruption for that transplant only. For purposes of this policy, immediate and permanent non-function shall be defined as: (1) kidney graft removal within the first ninety (90) days of transplant evidenced by a report of the nephrectomy for the transplanted kidney or (2) kidney graft failure within the first ninety (90) days of transplant evidenced by documentation that the candidate is either: (a) on dialysis, or (b) has measured creatinine clearance/calculated GFR less than or equal to 20 ml/min on the date that is ninety (90) days following the candidate's kidney transplant. Waiting time will be reinstated upon receipt by the Organ Center of a completed Renal Waiting Time Reinstatement Form and the documentation described above. The OPTN contractor will notify the OPO serving the recipient transplant center of the relisting and forward a copy of the relisting form to that OPO.
- 3.2.5 Preliminary Stratification.** The acceptable donor size must be specified for every potential liver recipient on the Waiting List.
- 3.2.6 Waiting Time for Candidates in an Inactive Status.** Unless otherwise stipulated in each organ specific allocation policy, waiting time beyond 30 days shall not be accrued by candidates while they are registered on the Waiting List as being inactive.
- 3.2.7 Pancreas Waiting List Criteria.** Each candidate registered on the Pancreas Waiting List must be diagnosed with diabetes or have pancreatic exocrine insufficiency or require the procurement or transplantation of the pancreas for technical reasons as part of a multiple organ transplant.
- 3.2.8 Previous Kidney Donor Antigens Considered "Self" Antigens in Pancreas Match Runs.** Upon listing a candidate for pancreas after kidney transplantation, the transplant program has the option of entering the candidate's prior kidney donor's antigens, which will then be considered "self" antigens in pancreas match runs. In the event a candidate's prior kidney donor's antigens are entered, the match system for pancreas allocation will take into account the candidate's antigens and all of the kidney donor's mismatched antigens that are entered into UNetSM, Mismatches that are common to a candidate's prior kidney donor and a subsequent pancreas donor are considered as matches and the candidate will appear on the match-run print out for all pancreas donors who meet these mismatch criteria. Use of these modified mismatch criteria is optional.
- 3.2.9 Combined Kidney-Pancreas Waiting List Criteria.** Each candidate registered on the Kidney-Pancreas Waiting List must be diagnosed with diabetes or have pancreatic exocrine insufficiency with renal insufficiency.
- 3.2.10 Waiting Time Adjustment for Candidates Needing a Life-Saving Organ Transplant When the Need for a Second Organ Transplant Arises.** Waiting time accrued by a candidate for a transplant of a life-saving organ while waiting on the Waiting List may also be accrued for a second organ, when it is determined that the candidate requires a multiple-organ transplant. For purposes of this policy, a life-saving organ shall be defined as the heart, lung or liver. Kidney, pancreas or intestine may qualify as life-saving organs if routine alternative therapies are not possible and demonstrable and after all transplant centers and programs within those centers, the other transplant programs within the OPO and the OPO itself agree to the waiting time adjustment.